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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,293	04/04/2001	Mike Farwick	P 280108 000561 BT	4063
909	7590	01/13/2004	EXAMINER	
PILLSBURY WINTHROP, LLP			FRONDA, CHRISTIAN L	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	

1652

DATE MAILED: 01/13/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,293

Applicant(s)

FARWICK ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-45 is/are pending in the application.
- 4a) Of the above claim(s) 37,38,44 and 45 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27,35 and 36 is/are allowed.
- 6) ☒ Claim(s) 20-26,28-34 and 39-43 is/are rejected.
- 7) ☒ Claim(s) 23-26 and 28-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restriction

1. Newly submitted claims 37, 38, 44, and 45 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 37 and 38 are directed to any bacterium containing an attenuated mikE17 gene which is expected to differ in structure and sequence from the wild-type mikE17 polynucleotide of SEQ ID NO:1; and claims 44 and 45 are directed to hybridization probes which are placed in a classification (class 536, subclass 24.32) which is different from the originally elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37, 38, 44, and 45 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 20-36 and 39-45 are under consideration in this Office Action. The rejections stated in the previous Office Action dated 9/9/2002 (Paper No. 17) has been withdrawn. New rejections have been stated in the instant Office Action.

Claim Objections

3. Claims 23-26 and 28-31 are objected to because the claims expand the scope of claims 20 and 27, respectively. Applicant is required to rewrite the claims in independent form.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 23-26, 28-34, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a protein

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comprising SEQ ID NO: 2, an isolated polynucleotide of the nucleotide sequence of nucleotides 252-1673 of SEQ ID NO: 1, an isolated polynucleotide of the nucleotide sequence SEQ ID NO: 1, ; does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants' arguments filed 6/13/2002 (Paper No. 16) have been fully considered but they are not persuasive. Applicants' position is that it would not take undue experimentation to synthesize the claimed invention and that the invention is enabled by the guidance provided in the specification. The Examiner disagrees with Applicants' position for the reasons of record as supplemented below.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any isolated polynucleotide encoding a protein with an amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to that of SEQ ID NO: 2 and any isolated polynucleotide which is at least 70%, 80%, 90%, or 95% identical to SEQ ID NO: 1.

The specification provides guidance and examples for making an isolated polynucleotide encoding a protein comprising SEQ ID NO: 2 and an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1. However, the specification does not teach the specific catalytic/binding amino acids and the structural motifs which are essential for protein/enzyme structure and activity/function.

The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed polynucleotides is enormous and entails selecting specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in a polynucleotide

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encoding SEQ ID NO: 2 or a polynucleotide of SEQ ID NO: 1 to make the claimed polynucleotide encoding a protein with an amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to that of SEQ ID NO: 2 or polynucleotide which is at least 70%, 80%, 90%, or 95% identical to SEQ ID NO: 1 and determining by assays whether the polynucleotide encodes a functional protein. The specification does not provide guidance with respect to the specific binding/catalytic amino acids and the structural motifs essential for protein/enzyme structure and activity/function which must be preserved. Thus, searching for the specific nucleotides to change (nucleotide deletion, insertion, substitution, or combinations thereof) in a polynucleotide encoding SEQ ID NO: 2 or a polynucleotide of SEQ ID NO: 1 to make the claimed invention is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polynucleotide encodes a functional protein is extremely low since no information is provided by the specification regarding the specific binding/catalytic amino acids and the structural motifs essential for protein/enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for protein/enzyme structure and activity/function which must be preserved.

6. Claims 23-26, 28-34, 39, 40, and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 6/13/2002 (Paper No. 16) have been fully considered but they are not persuasive. Applicants' position is that the written description requirement has been met although the claims encompass a very large number of compounds and structures. The Examiner disagrees with Applicants' position for the reasons of record as supplemented below.

The claims are directed to any isolated polynucleotide encoding a protein with an amino acid sequence that is at least 70%, 80%, 90%, or 95% identical to that of SEQ ID NO: 2; any isolated polynucleotide which is at least 70%, 80%, 90%, or 95% identical to SEQ ID NO: 1; any polynucleotide that hybridizes to the complement of SEQ ID NO: 1. The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 1. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties for which no predictability of structure is apparent.

There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification does not provide a written description of the entire genus encompassed by the claims where the biological function and utility of the members of the genes have yet to be discovered and described.

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Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is vague and indefinite because the meets and bounds of the phrase “degenerate variants thereof” are not clear. It is not certain when a polynucleotide is or is not a “degenerate variant” of the claimed invention.

Regarding claim 20, the phrase "may be used" renders the claim indefinite because it is unclear whether the limitation following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Furthermore, it is not known how the claimed polynucleotide by itself can increase the production of amino acids.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Reeves et al. (Accession AAA14663).

Reeves et al. (Accession AAA14663) teach a polynucleotide “consisting essentially of nucleotides 252-1673 of SEQ ID NO: 1 (see attached alignment). Thus, the reference teachings anticipate the claimed invention.

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11. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Murdin et al. (Accession AAZ61503).

Murdin et al. (Accession AAZ61503) teach a polynucleotide encoding a protein "consisting essentially of the amino acid of SEQ ID NO: 2 (see attached alignment). Thus, the reference teachings anticipate the claimed invention.

12. Claims 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Schauwecker et al. (Accession AAF25795).

Schauwecker et al. (Accession AAF25795) teach a polynucleotide that is expected to hybridize to SEQ ID NO: 1 since the claim is not limited to the stringent hybridization temperature of 68°C (see attached alignment). Thus, the reference teachings anticipate the claimed invention.

Conclusion

13. Claims 27, 35, 36 are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1300